K002676

OCT 3 0 2000

GUIDANT

510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax number of the Applicant

Guidant Cardiac & Vascular Surgery Group
1525 O'Brien Drive
Menlo Park, CA 94025

Telephone: (650) 470-6200
Fax: (650) 617-5024

B. Contact Person

Kristen Honl
Regulatory Affairs Manager

C. Date Prepared

August 25, 2000

D. Device Name

Trade Name: ENDOvance™ DualPASS™ Tear-Away Sheath Introducer
Classification Name: Catheter Introducer, Class II

E. Device Description

The ENDOvance DualPASS Tear-Away Sheath Introducer is a disposable device that consists of a dual lumen sheath and an inner dilator.

The ENDOvance DualPASS is designed to provide access to tortuous and calcified arteries. The dual lumens are designed to aid in the prevention of wire wrapping.

F. Intended Use

The ENDOvance DualPASS Tear-Away Sheath Introducer is indicated for use in assisting with introduction of diagnostic or therapeutic devices into the body.

G. Substantial Equivalence

The ENDOvance DualPASS Tear-Away Sheath Introducer is substantially equivalent to the Angetear Tear-Away Sheath Introducer and the Endologix Dual Lumen Catheter. Both of which have been cleared by the Food and Drug Administration. The design of the ENDOvance DualPASS Tear-Away Sheath Introducer is based on the Angetear Tear-Away Sheath Introducer. The ENDOvance DualPASS and Endologix devices both consist of two lumens. The predicate devices are substantially equivalent in intended use, design, materials, technology characteristics and components to the ENDOvance DualPASS Tear-Away Sheath Introducer.

H. Device Testing Results and Conclusion

Table A-1: Bench Test Results

Bench Test	Pass/Fail
Dilator/Hub Joint Testing	Pass
Guidewire from Dilator Tip Separation Force Test	Pass
Hub Joint Test	Pass
Leak Rate Test	Pass
Functional Testing	Pass

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 0 2000

Ms. Kristen Honl
Regulatory Affairs Manager
Guidant Cardiac & Vascular Surgery Group
1525 O'Brien Drive
Menlo Park, CA 94025

Re: K002676
Trade Name: ENDOvance™ DualPASS™ Tear-Away Sheath Introducer
Regulatory Class: II
Product Code: 74 DYB
Dated: August 24, 2000
Received: August 28, 2000

Dear Ms. Honl:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 002676

Device Name: ENDOvance™ DualPASS™ Tear-Away Sheath Introducer

Indications For Use: The ENDOvance DualPASS Tear-Away Sheath Introducer is indicated for use in assisting with introduction of diagnostic or therapeutic devices into the body.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002676

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)